

REMARKS

The Office Action indicates that claims 1-8, 10-14 and 18 are examined herein and that claims 9 and 19-29 are withdrawn pursuant to a restriction requirement. Claims 1, 2, 10, 12-14 and 18 are amended herein.

Claims 1-8, 10-14 and 18 are rejected as not enabled with respect to preventing or inhibiting extracellular matrix build-up. The Office concedes, however, that the claims are enabled with respect to treating or reducing extracellular matrix build-up. Applicant is amending the claims herein to avoid using the terms "preventing" and "inhibiting" herein, and submits that this rejection is overcome.

Claims 1-8 are rejected as anticipated by WO 03/020215 (hereinafter "Goldstein"). The reference is considered to anticipate because it assertedly discloses a method "for promoting healing or preventing damage to coronary tissue," as evidenced by Goldstein's claims.

The claims here are not drawn to methods for promoting healing or preventing damage, as discussed in Goldstein. Goldstein refers to healing of coronary tissue that has been damaged or injured and does not attribute treating or reducing extracellular matrix build-up in a tissue or vessel to Thymosin beta 4 (T β 4). Therefore, there can be no anticipation. Further, Goldstein makes no direct link between mesenchymal epithelial differentiation (the activity Goldstein teaches for T β 4) and an ability to treat the condition of plaque build-up or to reduce plaque build-up. There is no guidance whatsoever that points the skilled artisan toward a method for treating or reducing extracellular matrix since there is no suggestion or even a hint that T β 4 might have this activity. Goldstein only suggests that damage to tissue can be treated, not that plaque deposition can be treated or reduced, these are not the same, and have not been connected in the cited reference.

In summary, the Office has not been able to show that Goldstein meets all limitations of the claims presented here or that Goldstein even suggests all of these features. Applicant therefore requests withdrawal of this rejection.


Claims 1-8, 10-14 and 18 are rejected as obvious over Goldstein, discussed above. In order to make out a case of prima facie obviousness, the Office is required to show that there is some fair suggestion of the invention as claimed, in the art reference. Goldstein does not even mention the possibility that T β 4 could have any activity that affects extracellular matrix build-up. Goldstein teaches only to use T β 4 to promote repair, healing and prevention of tissue damage and preventing degenerative changes in the tissue. There is no suggestion or guidance that would have lead the person of skill to believe that T β 4 would reduce or treat the condition of extracellular matrix deposition, and the Office has not even asserted as much. Healing of tissues that have been damaged or that T β 4 enhances endocardial/mesenchymal, transformation in vitro (see example 1) suggests only a connection to forming heart valves and restoring functionality of damaged tissue. Goldstein therefore does not fairly suggest the method which is claimed, and provides no expectation that plaque build-up could be treated or reduced, much less a reasonable expectation.

Applicant request that the Office consider the remarks above, and those made in the context of anticipation, and withdraw this rejection.

Applicant requests reconsideration of the application and the claims as amended, and allowance of all claims at this time.

Respectfully submitted,

By



Martha Cassidy
Attorney for Applicants
Registration No. 44,066
ROTHWELL, FIGG, ERNST & MANBECK, P.C.
Suite 800, 1425 K Street, N.W.
Washington, D.C. 20005
Telephone: (202)783-6040